REMARKS

Claims 1-8, 10, 15-16, 18-21, and 25 have previously been cancelled to expedite prosecution. Claim 17 stands withdrawn from consideration as being directed to non-elected species.

Applicants' invention, as delineated by remaining claims 9, 11-14, 22, 24, and 26, as amended, is directed to a surgical implement detection system for detecting surgical implements within a wound at the conclusion of a surgical procedure. Compared to previously-known markers for article detection systems, the present inventive marker has a significantly reduced size. As a result, the marker is readily attached or similarly associated with surgical implements, including both reusable surgical tools, disposable items such as surgical sponges, or other like articles. The marker has a plurality of magnetostrictive amorphous metal strips disposed in a cavity with their orientation being non-parallel. The multiple directions greatly enhance the sensitivity of the marker to interrogating fields having different directions, thereby markedly increasing, if not assuring, the detection of the marker and a surgical implement associated therewith while the implement is still located within a patient's body during surgery. The marker's smaller size permits it to be attached to items that otherwise could not be protected. In some cases, a surgical item is simply too small to accommodate a conventional marker. The item may be smaller than the typical 1.5" length of a marker operative at about 60 kHz, or it may have no suitable location large enough for such a marker to be placed on it. In other instances, a conventional marker accompanying an item or attached to it would be an impediment to the item's ordinary use, e.g. by interfering with a surgeon's manipulation of the item. Applicants maintain that the prior art has failed to recognize

the potential for a smaller, more widely applicable marker that could avoid these detriments.

The problem of implements left behind after the completion of surgical procedures remains a serious and vexing medical issue, because if undetected, these items are highly likely to cause serious, and possibly fatal, injury to a patient. The present system provides a procedure whereby these items can be reliably, quickly, and efficiently detected in the harried and intense environment of an operating room, even prior to the completion of the surgical procedure and closure of the surgical wound, thereby avoiding the risk of infection and other injury to the patient, and obviating the need for further invasive, deleterious, and painful follow up care otherwise inexorably required.

The Examiner's withdrawal of the rejection of claims 1-5, 14-16, 18, 19, and 22 under 35 USC 102(b) as being anticipated by or, in the alternative, under 35 USC 103(a) as obvious over US Patent No. 5,057,095 to Fabian, is noted with appreciation.

Claims 9, 11-14, 22, 24, and 26 stand rejected under 35 USC 103(a) as obvious over US Patent No. 5,057,095 to Fabian, in view of US Patent No. 5,338,373 to Von Hoene et al.

Fabian discloses a surgical implement detector utilizing a resonant marker. In one embodiment, the Fabian marker is magnetomechanical.

With respect to claims 12-14, 22, and 26, the Examiner has stated that Fabian teaches a system for detecting surgical implements using a magnetomechanical marker having a resonant frequency, which applicants acknowledge. The Examiner further indicated that the Fabian system provides three types of resonance, magnetomechanical, electromechanical, and electromagnetic. It is important to recognize that Fabian's

disclosure an overall upper bound of 1 GHz for the resonant frequency is made only in the general context of all systems of all three types. However, there is no disclosure or suggestion that systems embodying each of the three types of resonance (magnetomechanical, electromechanical, and electromagnetic) may be constructed to operate at frequencies approaching 1 GHz. The Examiner has taken cognizance of applicants' citation of col. 8, lines 9-10 of Fabian as being the only guidance provided as to the operating frequency of a magnetomechanical system, namely that the frequency be one "used by a conventional system."

The Examiner has acknowledged that Fabian fails to teach a specific range of frequencies or a plurality of magnetostrictive strips disposed in a cavity in non-parallel orientation, as recited by base claims 14, 22, and 26 and claims 9, 11-13, and 24 various dependent thereon.

Accordingly, he has pointed further to Von Hoene et al. as allegedly motivating the skilled person to employ strips of different lengths to allow different articles to be detected. He has specifically pointed to an example of a resonant strip having a length of 1.8 cm and a resonant frequency of 120.21 kHz.

As set forth at page 8, line 19 to page 9, line 3; page 18, lines 1-15; and page 18, line 23 to page 19, line 10, a marker constructed to operate within applicants' claimed frequency range advantageously is smaller in size than conventional magnetomechanical markers used in connection with a surgical implement, such as that disclosed by Fabian, but nevertheless has an adequate volume of magnetic material to emit a signal that is large enough to permit highly reliable, rapid detection of the marker in the adverse environment of surgery.

There is nothing in Fabian, even in light of VonHoene et al., to suggest such a reconstruction. Clearly, speed and reliability of detection are of paramount importance in

such a situation. On the other hand, increasing the operating frequency of the detection system necessarily decreases the length of the resonant element of the marker. In addition, the reducing the length also typically necessitates decreasing the width of the element in order to maintain a comparable demagnetizing factor. The decrease in total element volume in turn inherently reduces the signal output the marker provides. The prior art has thus eschewed shorter, higher frequency markers, regarding them as providing inadequate output to permit reliable marker detection. On the other hand, applicants' marker is capable of providing sufficient output as a result of the particular configuration taught. Advantageously, the compact size of the present marker permits surgical items to be tagged that would be physically impossible to tag using larger conventional markers. As set forth above, many surgical items either do not have a suitable location on which to situate a conventional marker, or the use of the item would be adversely impacted by the presence of the marker. On the other hand, the smaller markers provided by applicants can be used beneficially in such situations. The non-parallel orientation of the strips in the marker further enhance the probability that the marker will, in fact, be detected during its appointed use during surgery.

Applicants respectfully submit that Von Hoene et al. fails to disclose or suggest any marker configuration that involves a magnetostrictive element having multiple, non-parallel resonant strips of amorphous metal. Accordingly, Von Hoene et al. does not cure the deficiency of Fabian.

Furthermore, the Von Hoene et al. reference is directed to a method of encoding and decoding a glassy alloy strip to be used as an identification marker. Attention is further drawn to the disclosure at col. 4, lines 18-24, in which the patentees state that "The fundamental aspect of this invention is that the modification to the alloy strip be of such a nature as to change the effective length of the marker. The effective length of an

alloy strip may be calculated for a modified strip by using the physical length and resonant frequency of an unmodified strip having the same composition."

While Von Hoene et al. admittedly discloses in Table I a magnetomechanically resonant strip having a resonant frequency of 120.21 kHz, it is submitted that such disclosure falls short of rendering obvious the use of such a strip in a marker appointed for an EAS system, let alone a marker attached to a surgical instrument so as to render such instrument detectable in the manner provided by applicants' invention. The object of the Von Hoene et al. invention, to the contrary, is to provide a large plurality of unique and measurably discernable markers (see, e.g., col. 2, lines 46-59), wherein the resonant frequency is determined by the effective length of a marker element, not the actual length. Nothing in Von Hoene et al. contemplates or suggests the use of any marker having a 120.21 kHz resonant frequency, let alone such a marker in a medical or surgical context. To the contrary, the various techniques for modifying the effective length of marker disclosed by Von Hoene et al. were all implemented using markers having a resonant frequency of about 55-69 kHz, as provided in Examples 2-7. The Examiner has suggested that Von Hoene et al. teaches changing the length of the marker. However, he has relied on a passage that relates to changes in effective length resulting from particular processing and not from changes in the actual length of the marker element.

By way of contrast, the present invention provides a marker attachable to a surgical instrument, the marker being of significantly reduced size compared to conventional markers operating at lower frequency. As a result, the marker enables the reliable, quick, and efficient detection of retained instruments in the harried and intense environment of an operating room, even prior to the completion of the surgical procedure and closure of the surgical wound, thereby avoiding the risk of infection and other injury to the patient, and obviating the need for further invasive, deleterious, and painful follow

up care otherwise inexorably required. The small size further permits instruments to be tagged that could not be tagged with larger prior art markers. None of these beneficial attributes is afforded by any marker or tagged instrument constructed in accordance with the teachings of Fabian and Von Hoene et al., even if taken in combination.

It is thus respectfully submitted that even in combination, Fabian and Von Hoene et al. do not disclose or suggest the method of claim 14, the surgical implement of claim 22, or the system delineated by claim 26, as amended.

The Examiner has further referred to "Irizarry et al" and "Herzer." However, neither reference is further identified in the present Office Action, let alone is either included in the aforementioned statement of rejection. Applicants presume that the Examiner has in view US Patent Publication No. 2002/0005783 to Irrizary et al. and US Patent 6,359,563 to Herzer, both references having been cited in earlier Office Actions in this application. Irrizary et al. provides a child monitoring device, while Herzer provides a magneto-acoustic marker for electronic article surveillance said to have reduced size and high signal amplitude. It is further presumed that the Examiner intended to reject claims 9, 11-14, 22, 24, and 26 over a further combination with one or both of the Irizzary et al. and Herzer references, and not just the two Fabian and VonHoene references actually set forth. If another rejection or references other than the foregoing were intended, the Examiner is respectfully requested to vacate the present Office Action and issue a corrected Office Action.

The Examiner alleges that Irizarry et al. teaches a magnetomechanical maker employing two non-parallel strips to increase the detection rate of the marker and that it would have been obvious to include "the concept of non-parallel strips as taught by Irizarry et al. with the marker taught by the combination of Fabian, VonHoene et al. and

Herzer to provide the benefit of increasing the detection rate of the marker, as taught in paragraph [0034] of Irizzary et al."

Significantly, the embodiment of Irizarry to which the Examiner likely refers, i.e. that depicted by Irizzary's Fig. 2, is said to be a tag that includes two magnetomechanical markers. *See* paragraph [0025]. Irizzary et al. indicates that the improved detection is afforded by provision of multiple markers oriented in different directions. Each marker includes a distinct magnetomechanical element and a distinct bias element. *See* paragraphs [0034] and [0036]. Clearly, Irizzary et al. does not contemplate a structure in which a single marker employs plural, non-parallel magnetomechanical elements housed in a single cavity.

More specifically, applicants respectfully submit that the tag of Irrizary et al. comprises two magnetomechanical markers, having elongated axes that are perpendicular. Whereas each of the mechanical markers (e.g. markers 25 and 26 of tag 21 shown in Fig. 2) of Irrizary et al. separately includes a magnetomechanical elongated strip, applicant's marker includes a magnetomechanical element comprising a plurality of elongated strips. Present claim 26 recites in feature (a)(iii) a housing having a cavity enclosing the magnetomechanical element (a plurality of elongated strips, from feature (a)(i)) disposed in the cavity in a non-parallel orientation with their centers coincident. Therefore, it is respectfully submitted Irrizary et al. does not disclose a marker wherein a magnetomechanical element comprises plural strips that collectively constitute a magnetomechanical element and are together enclosed in a cavity of a housing. Rather, the Irrizary et al. marker comprises multiple magnetomechanical elements that are enclosed in cavities in separate housings, even if the multiple markers are mechanically joined. Irizzary et al. further fails to disclose or suggest the particular resonant frequency

range delineated by applicants, thereby failing to cure the aforementioned deficiency, even if all the applied references are taken in combination.

On the other hand, Herzer alleges improved marker response by provision of multiple magnetomechanical strips in parallel orientation. Moreover, the reduction in size afforded by Herzer is attained by use of narrower magnetostrictive ribbon, e.g. ribbon 6 mm wide instead of the 12.7 mm wide ribbon that is said to be conventional. The resonant element in Herzer remains rectangular, with no recognition of shortening the long dimension of the marker, which is typically about 1.5 inches as required to maintain an operating frequency of about 55-60 kHz.

Like Fabian and VonHoene et al. as discussed above, Herzer does not disclose or suggest any marker configuration employing multiple resonator strips that are non-parallel.

While the parallel strip orientation of a Herzer marker may provide some improvement in the detectability of a Herzer marker that is favorably oriented with respect to a detection apparatus, it does not provide any solution to the problem recognized by Irrizary et al. of response by unfavorably oriented markers. *See* lines 9-15 of paragraph [0034] of Irrizary et al. Only in light of applicants' own teaching is there recognition that non-parallel strips, housed in a single cavity, provides improved orientation detectability without necessitating the impermissible operation of hindsight and the far more difficult and complex construction required by the Irrizary et al. multiple-marker construction.

Even less is there any suggestion of the preferred configuration delineated by claim 24, in which a bias magnet is disposed between resonant strips. By way of contrast, Herzer depicts a configuration in which both resonator strips are on a single side of a bias element, all these elements being elongated and in generally parallel disposition.

Applicants maintain that there is no reasonable expectation that a multiple, non-parallel configuration constructed with a single elongated bias element on one side, as provided by Herzer, would successfully operate for applicants' function. Neither is there any warrant for carrying out the substantial reconstruction that would be required to attain a marker of the type delineated by claim 24 based on the teachings of Fabian and VonHoene et al., whether or not combined with either or both of Irrizary or Herzer.

It is thus respectfully submitted that even in combination, Fabian, VonHoene et al., Herzer, and Irrizary et al. do not disclose or suggest the system delineated by applicants' claims 14, 22, and 26. Applicants maintain that claims 9 and 11-13 dependent from claim 26 and claim 24 dependent from claim 22 are patentable for at least the same reasons as their respective base claims.

Accordingly, reconsideration of the rejection of claims 9, 11-14, 22, 24, and 26 under 35 USC 103(a) as being unpatentable over Fabian and VonHoene et al., whether with or without the further addition of Herzer and/or Irrizary et al., is respectfully requested.

CONCLUSION

In view of the foregoing remarks, it is respectfully submitted that the present application has been placed in allowable condition. Reconsideration of the rejection of claims 9, 11-14, 22, 24, and 26 and allowance of the present application are, therefore, earnestly solicited.

Respectfully submitted,

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